(FINAL/APPROVED 12/16/2009)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 2, 2009
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

CALL TO ORDER:	The meeting was called to order at 9:03AM.
PRESIDING:	Jennifer H. Edwards, Chair
MEMBERS PRESENT:	Gill B. Abernathy John O. Beckner Willie Brown Gerard Dabney David C. Kozera Leo H. Ross Michael E. Stredler Brandon K. Yi, Vice Chair
MEMBERS NOT PRESENT:	Bobby Ison
STAFF PRESENT:	Caroline D. Juran, Deputy Executive Director Howard M. Casway, Senior Assistant Attorney General Elaine Yeatts, Senior Policy Analyst Sandra Whitley Ryals, Director, DHP Sammy Johnson, Deputy Director of Enforcement Sharon Davenport, Administrative Assistant
QUORUM:	With nine members present, a quorum was established.
APPROVAL OF AGENDA:	An amended agenda was distributed prior to the beginning of the meeting.
APPROVAL OF MINUTES:	The Board reviewed draft minutes included in the agenda package. With no changes to the minutes, the minutes were approved as presented.
PUBLIC HEARING ON PROPOSED REGULATIONS ON UNPROFESSIONAL CONDUCT:	The Board held a public hearing on proposed regulations to establish regulations on unprofessional conduct. There was no comment offered on the proposed regulations during the hearing.
DHP DIRECTOR'S REPORT	Ms. Ryals discussed the Revenue and Expenditure Analysis. She explained that the Board has a revenue surplus which exceeds the 10% allowance and therefore, suggested that the Board adopt a one-time reduction for renewal fees due on or before December 31, 2009, February 28, 2010 and April 30, 2010. She stated that a permanent reduction is not recommended as the Board's

expenditures are projected to exceed revenue in 2011. Ms. Edwards asked if the analysis included the agency's increased costs associated with information technology services and Ms. Ryals acknowledged that the analysis did include this information.

Additionally, Ms. Ryals reviewed the patient care disciplinary case processing times and stated that the agency has met and exceeded the goals set for clearance rate, age of pending caseload and time to disposition. During the fourth quarter of fiscal year 2009, the agency's clearance rate was 114%, age of pending caseload was 9.5%, and time to disposition was 92%. She then reviewed statistics specific to the Board and stated that during the fourth quarter of fiscal year 2009, the clearance rate was 71%, age of pending caseload was 9%, and time to disposition or the percent of patient care cases closed in 250 business days was 100%. She applauded the Board's achievements remarking that huge progress had been made. She, also, emphasized the importance of continuing to strive for a 100% clearance rate to prevent a future backlog of cases. Ms. Ryals, also, applauded the Board's efforts in recently reviewing the inspection process and stated that an efficient and meaningful inspection program would be key to continuing forward progress.

LEGISLATION UPDATE:

Ms. Yeatts stated that the agency has submitted a legislative package to the executive branch to review. The Board has one legislative proposal which is the annual scheduling bill that the Board reviewed and approved in June which conforms Virginia schedules of controlled substances to federal regulations. Additionally, she stated that a second agency legislative proposal regarding the use of agency subordinates in informal conferences may impact on the Board.

REGULATION UPDATE:

Ms. Yeatts provided an update on current regulation processes which included a statement that the final amendments to regulations from the periodic review became effective September 2, 2009.

ADOPTION OF FINAL REGULATIONS ON EXPIRATION/RENEWAL DATES:

Ms. Yeatts explained that the Board needed to adopt final regulations to replace emergency regulations that had changed the expiration dates for facilities in order to stagger the Board's workload in renewing its licenses. The public comment period on proposed regulations ended on 8/7/2009 with no public comment filed.

Motion:

The Board voted unanimously to adopt the proposed amendments to expiration dates for facilities without any change as final regulations. (motion by Kozera, second by Beckner)

FAST TRACK REGULATIONS FOR CHANGES TO STAT BOXES:

Ms. Juran reminded the Board of the request at the June 2009 meeting of the Virginia Health Care Association (VHCA) for changes in the regulation related to stat-drug boxes in long term care facilities. Specifically, VHCA was requesting Schedule II oral drugs be allowed in the boxes to cover initiation of pain treatment while waiting for orders to be filled by the provider pharmacy. The Board Chairman had appointed an ad hoc committee at that meeting to work with representatives of LTCF pharmacy to develop a recommendation for changes prior to this Board meeting, but the ad hoc committee was unable to meet. Board staff did work with key parties to develop draft language to present to the full Board. Ms. Juran reviewed this draft language with the Board. The draft language allows for no more than 20 oral solid dosage units of each schedule in Schedules II-V per box with a conversion allowance for liquids. Additionally, the Board reviewed public comment from Jack Gross, General Manager of PharMerica-Virginia Beach, who did not oppose the draft changes prepared by staff and VHCA, but suggested an alternative plan which included combining the drugs in Schedules II-V from the emergency drug kit and the stat-drug box into one kit. The Board, also, heard comment from Wendy Walter, Fairmont Crossing, Amherst, VA, Hill Hopper, General Manager of NeighborCare Richmond, and Joseph Ward, MD regarding the two proposed changes for stat-drug boxes and the immediate need to have Schedule II pain medications readily available in the stat-drug box to meet nursing home patients' needs. After some discussion, the Board determined that while Mr. Gross' suggestion had merit it would require a change to both 18VAC110-20-540 and 18VAC110-20-550 and should possibly be considered during the next regulatory review process. Additionally, the Board determined that there would likely not be any opposition to the draft amendment as prepared by staff and key parties and thus could be adopted using the fast-track process.

Motion:

The Board voted unanimously to adopt, as a fast-track regulation, the draft amendments to 18 VAC 110-20-550 prepared by staff. (Attachment A) (motion by Stredler, second by Brown)

ADOPTION OF REDUCTION IN RENEWAL FEES FOR 2009/2010:

To address the revenue surplus issue discussed earlier in the meeting, Ms. Yeatts presented draft amendments to three sets of Board regulations that would provide for a one-time fee reduction for the next renewal cycle for all licensees. Additionally, Ms. Yeatts explained that fee reduction is an exempt action under the Administrative Process Act.

Motion:

The Board voted unanimously to adopt the reduction in renewal fees for 2009/2010 as presented. (Attachment B)

(motion by Kozera, second by Stredler)

CORRECTION OF CITE IN REGULATION 18VAC110-20-106

Ms. Yeatts explained that an error was made during the recent periodic regulatory review process. The cite reference to 18VAC110-20-90 in Regulation 18VAC110-20-106 was stricken, however, the intention was to reference both 18VAC110-20-90 and 18VAC110-20-100. Ms. Yeatts stated that the correction would be exempt from the Administrative Process Act.

Motion:

The Board voted unanimously to adopt the exempt regulation change to add the reference to subsection B of 18VAC110-20-90 back into Regulation 18VAC110-20-106 as presented in the agenda package. (Attachment D) (motion by Abernathy, second by Beckner)

UPDATE ON ACTION ITEMS:
REPORT OF AD HOC COMMITTEE ON INSPECTION PROCESSESS:

Ms. Juran provided the Board with an informal recommendation of the ad hoc committee, appointed by the Board at its last meeting and which met on July 17, 2009 and August 26, 2009 to develop a recommendation for streamlining the inspection program and developing standard sanctions for expedited consent orders. The plan is that these expedited consent orders based on approved standard penalties would be offered by the pharmacy inspectors at the conclusion of the inspection. After reviewing numerous deficiencies to determine appropriate disciplinary action, the committee recommended that individual deficiencies believed to be more egregious or "major" should be assigned a monetary penalty which would be imposed on the pharmacy permit when found in violation, unless the pharmacy requested an informal conference to review the possible violation. Additionally, the committee recommended that other deficiencies believed to be less egregious or "minor" should be listed together and that a $250 monetary penalty would be imposed against the pharmacy permit when any three deficiencies from this list was cited. For each additional deficiency over three from this list, another $100 monetary penalty per deficiency would be imposed. Any pharmacy that does not consent to the standard penalty would be scheduled for an informal conference, most likely before an agency subordinate.

The Board reviewed and discussed the committee's recommendations related to major and minor deficiencies. The Board made several changes to the list. Mr. Yi stated that he supported the concept of imposing monetary penalties against a pharmacy permit, but expressed concern regarding the public information which could result. He stated that a pharmacy owner may not be able to control the individual actions of the employed pharmacists and feared the public information associated with the violations may be unfair to the pharmacy owner.

Lastly, Sammy Johnson, Deputy Director of Enforcement stated that a new pharmacy inspection report would be created to reflect the identified deficiencies and would be posted online for public view when ready.

Motion:

The Board voted 8-1, with Mr. Yi voting no, to adopt the process for pharmacy inspectors to offer a pharmacy an expedited consent order to which the pharmacy may choose to immediately pay the standard monetary penalties associated with the deficiencies as presented by the committee and amended by the Board, and to make these standard monetary penalties a Board guidance document. (motion by Beckner, second by Kozera) (Attachment C)

Action item:

Ms. Abernathy requested staff to provide a progress report following 6 months from implementation. Ms. Ryals stated that she would suggest a progress report be given by staff at each Board meeting.

MISCELLANEOUS: SPECIAL-USE PERMITS FOR PSDS WANTING TO SELL 2-3 TOPICAL PRODUCTS, I.E., LATISSE, 4% HYDRO-QUINONE, AND TRETINOIN CREAM; WAIVERS:

Ms. Juran stated that staff has received written requests from two different physicians requesting waivers from specific regulations regarding practitioners of the healing arts to sell controlled substances. One physician wishes to only dispense Latisse. The second physician wishes to dispense Latisse and perhaps other topical cosmetic products such as hydroquinone. Ms. Juran explained that other physicians have telephoned the Board office in the past requesting waivers for dispensing tretinoin creams. Physicians have specifically requested a waiver of the alarm system or outside monitoring of the alarm and the restricted access provision to the drug stock. Ms. Juran commented that the Board could waive the requirements, for good cause shown, through the issuance of a limited-use license as stated in 18VAC110-20-30 when the scope, degree or type of services provided to the patient is of a limited nature. After some discussion, the Board determined that good cause had not been shown and therefore, denied the request for the aforementioned waivers.

Motion:

The Board voted unanimously to deny the request for waivers of restricted access and alarm requirements by the two physicians. (motion by Beckner, second by Ross)

BOARD INTERPRETATION OF NEW LANGUAGE IN 18VAC110-20-270:

Ms. Juran explained that staff had received a number of comments after the publication of final regulations from pharmacists who were very concerned with the elimination of ratios from the regulations and who felt that corporate decisions would be made on staffing and that employee pharmacists would have no say as to how many persons they may safely supervise. Additionally, while ratios were removed from regulation, staff realized that statute still includes a maximum ratio of 1:4, pharmacist to pharmacy

technicians. Additionally, Ms. Juran stated that since the new regulation does not directly address ratios, but the statute does, there is some confusion as to the Board's expectation. Most recently, staff received a phone call from a chain pharmacy that wants to establish a primary training pharmacy with 1 pharmacist supervising 4 pharmacy technicians and 4 pharmacy technician trainees at one time. The pharmacist questioned staff whether this would meet compliance. Because of these recent issues, Ms. Juran stated that staff was requesting that the Board interpret the new regulation in the context of the statute to determine how many pharmacy technicians and pharmacy interns a pharmacist may safely supervise at one time.

Mr. Casway advised the Board that, in his reading of §54.1-3320, no pharmacist shall supervise more than four persons performing pharmacy technician duties at one time, regardless of whether this person performing pharmacy technician duties is a registered pharmacy technician, technician in training or pharmacy intern. Additionally, he stated that he believed if the pharmacy intern was gaining hours of practical experience and therefore, performing duties restricted to a pharmacist, then the pharmacy intern would not be considered part of the 1:4 pharmacist to pharmacy technician ratio. Lastly, Mr. Casway advised the Board that the new regulation appears to be in direct conflict with statute and suggested adopting an exempt amendment to the regulations to address the conflict.

Motion:

The Board voted unanimously that the restriction in §54.1-3320 of one pharmacist supervising no more than four pharmacy technicians is interpreted to mean that a pharmacist shall not supervise more than four persons performing pharmacy technician duties at one time, regardless of whether this person performing pharmacy technician duties is a registered pharmacy technician, technician in training or pharmacy intern; that pharmacy interns gaining hours of practical experience and therefore, performing duties restricted to pharmacists, under direct monitoring by the pharmacist, shall not be considered part of the 1:4 pharmacist to pharmacy technician ratio; and the Board to adopt an exempt change to 18 VAC 110-20-270 to resolve the conflict with statute and clarify this issue. (motion Beckner, second by Stredler) (Attachment D)

SET MEETING SCHEDULE FOR 2010: ***see footnote for change to schedule**

The Board selected its 2010 meeting dates as follows:
March 10, 2010
June 2, 2010
September 1, 2010
November 30, 2010

REPORT ON BOARD OF HEALTH PROFESSIONS, JENNIFER EDWARDS:

Ms. Edwards stated that the Regulatory Research Committee continues to study the possible need to regulate genetic counselors and has determined that persons performing kinesiotherapy do not meet the qualifications for a profession to be regulated by this agency. Additionally, Ms. Edwards stated that she may soon be resigning from the Board of Health Professions due to conflicts with personal commitments.

NEW BUSINESS:

Ms. Abernathy requested that the Board take up this cause again now that federal regulations on the subject are in place. Additionally, she questioned whether the Board should establish a committee to review possible areas of pharmacy that may need regulating and for which no regulations currently exist. After a brief discussion, it was determined that a committee is not currently needed, but that these areas could possibly be identified during the next periodic regulatory review process.

ADJOURN:

With all business concluded, the meeting adjourned at 12:45 PM

Caroline D. Juran
Deputy Executive Director

Jennifer H. Edwards, Board Chair

Date

<u>*Note:</u> subsequent to the meeting, based on conference room and staff availability, three of the meeting dates had to be changed. The new schedule is as follows:

March 9, 2010-DHP-Conference Center, Board Room 4
June 2, 2010-DHP-Conference Center, Board Room 2
September 8, 2010-DHP-Conference Center, Board Room 2
December 15, 2010-DHP-Conference Center, Board Room 2

Project 2134 – Fast-track

BOARD OF PHARMACY

Stat-drug box in nursing homes

18VAC110-20-550. Stat-drug box.

An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:

1. The box is sealed in such a manner that will preclude the loss of drugs.

a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, time and name and quantity of item(s) removed. When the stat-drug box has been opened, it is returned to the pharmacy.

3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.

b. ~~The stat-drug box shall contain no Schedule II drugs.~~

~~c.~~ The stat-drug box shall contain no more than ~~one~~ 20 solid dosage units per schedule of Schedule ~~III~~ II through V ~~drug~~ drugs ~~in each therapeutic class and no more than five doses of each~~ except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit. If the unit of a liquid that may contain more than one dose is removed from the stat-box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.

Project 2110 – final exempt

BOARD OF PHARMACY

Fee reduction

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Nonresident pharmacy	$270
9. Controlled substances registrations	$90
10. Innovative program approval.	$250
If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	
11. Approval of a pharmacy technician training program	$150
12. Approval of a continuing education program	$100

D. Annual renewal fees.

1. Pharmacist active license	$90
2. Pharmacist inactive license	$45
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Physician permit to practice pharmacy	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Nonresident pharmacy	$270
9. Controlled substances registrations	$90
10. Innovative program continued approval based on board order not to exceed $200 per approval period.	

11. Approval of a pharmacy technician training program	$75 every two years

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy permit	$90
5. Physician permit to practice pharmacy	$90
6. Medical equipment supplier permit	$60
7. Humane society permit	$5
8. Nonresident pharmacy	$90
9. Controlled substances registrations	$30
10. Approval of a pharmacy technician training program	$15

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
d. Humane society permit	$30
e. Nonresident pharmacy	$115
f. Controlled substances registration	$180
g. Approval of a pharmacy technician training program	$75

G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50
2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35

I. For the annual renewal due on the stated dates, the following fees shall be imposed for a license, permit or registration:

1. Pharmacist active license – December 31, 2009	$50
2. Pharmacist inactive license – December 31, 2009	$25
3. Pharmacy technician registration – December 31, 2009	$15
4. Pharmacy permit – April 30, 2010	$210
5. Physician permit to practice pharmacy – February 28, 2010	$210
6. Medical equipment supplier permit – February 28, 2010	$140
7. Humane society permit – February 28, 2010	$20
8. Nonresident pharmacy – April 30, 2010	$210
9. Controlled substances registrations – February 28, 2010	$50

18VAC110-30-15. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Fee for initial license for a practitioner of the healing arts to sell controlled substances.

1. The application fee for initial licensure shall be $240.

2. The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500.

C. Renewal of license for a practitioner of the healing arts to sell controlled substances.

1. The annual fee for renewal of an active license shall be $90. For the annual renewal due on ~~before~~ December 31, ~~2006~~ 2009, the fee shall be $50.

2. The late fee for renewal of a license within one year after the expiration date is $30 in addition to the annual renewal fee.

3. The fee for reinstatement of a license expired for more than one year shall be $210.

D. The fee for reinspection of any facility shall be $150.

E. The fee for a returned check shall be $35.

18VAC110-50-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Initial application fees.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor	$270
6. Controlled substances registration	$90

C. Annual renewal fees.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor	$270
6. Controlled substances registration	$90

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Nonrestricted manufacturer permit	$90
2. Restricted manufacturer permit	$60
3. Wholesale distributor license	$90
4. Warehouser permit	$90
5. Nonresident wholesale distributor	$90
6. Controlled substances registration	$30

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Nonrestricted manufacturer permit	$240
b. Restricted manufacturer permit	$210
c. Wholesale distributor license	$240

d. Warehouser permit	$240
e. Nonresident wholesale distributor	$240
f. Controlled substances registration	$180

F. Application for change or inspection fees.

1. Reinspection fee	$150
2. Inspection fee for change of location, structural changes, or security system changes	$150
3. Change of ownership fee	$50
4. Change of responsible party	$50

G. The fee for a returned check shall be $35.

H. For the annual renewal due on ~~or before~~ ~~December 31, 2006~~ February 28, 2010, the following fees shall be imposed for a license or permit:

1. Nonrestricted manufacturer permit	$210
2. Restricted manufacturer permit	$140
3. Wholesale distributor license	$210
4. Warehouser permit	$210
5. Nonresident wholesale distributor	$210

Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$
1. No PIC or PIC not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. PIC in place, inventory taken, but application not filed with Board	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians performing duties on an expired license/registration (within 1 year)	18VAC110-20-80 and 18VAC110-20-105	per individual	100
5. Pharmacy technicians or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio	100
7. COL or remodel without application or Board approval	18VAC110-20-140	must submit an application	application fee 250
8. Refrigerator/freezer temperature out of range or not monitored	18VAC110-20-150		100
9. Alarm not operational or not being set	18VAC110-20-180 and 18VAC110-20-190		1000
10. Unauthorized access to alarm or locking device for Rx department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		500

Major Deficiency	Law/Reg Cite	Conditions	$
12. Storage of Rx drugs not in prescription department	18VAC110-20-190		500
13. No biennial inventory, or over 30 days late	54.1-3404 and 18VAC110-20-240		500
14. No incoming change of PIC inventory taken within 5 days	54.1-3434 and 18VAC110-20-240		500
15. Perpetual inventory not being maintained or monitored as required	18VAC110-20-240	will not be cited until 9/1/2010	250
16. Theft/loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240 and 18VAC110-20-250		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-425 and 18VAC110-20-420	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging, compounding, or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
21. Non-sterile compounding not in compliance with USP 795	54.1-3410.2		250
22. Sterile compounding not in compliance with USP 797	54.1-3410.2		1000
23. Compounding using ingredients in violation	54.1-3410.2		1000

Major Deficiency	Law/Reg Cite	Conditions	$
24. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
25. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
26. Security of after-hours stock not in compliance	18VAC110-20-450		500
27. For LTC, ADD being accessed for orders prior to pharmacist review and release	18VAC110-20-555		250

Minor Deficiencies

If three (3) or more minor deficiencies are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional minor deficiency over the initial three.

Minor Deficiency	Law/Regulation Cite	Conditions
General Requirements:		
1. Site specific training documentation not maintained as required	18VAC110-20-111	
2. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
3. Decreased hours of operation without public/Board notice	18VAC110-20-135	
4. No hot/cold running water	18VAC110-20-150	
5. Rx department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation

Minor Deficiency	Law/Regulation Cite	Conditions
6. Current dispensing reference not maintained	18VAC110-20-170	
7. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
8. Expired drugs in working stock or dispensed drugs being returned to stock not in compliance	18VAC110-20-200 18VAC110-20-355	10% threshold
9. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
10. Storage of will-call not in compliance	18VAC110-20-200	
11. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
12. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate	54.1-3404 and 18VAC110-20-240	
13. Records of receipt (invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
14. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
15. Prescriptions do not include required information	54.1-3408.01 and 54.1-3410	10% threshold
16. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
17. CII emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3

Minor Deficiency	Law/Regulation Cite	Conditions
18. Not properly documenting partial filling	18VAC110-20-320	
19. Offer to counsel not made as required	54.1-3319	per Rx
20. Prospective drug review not performed as required	54.1-3319	
21. Engaging in alternate delivery not in compliance	18VAC110-20-275	
22. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
23. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	
24. Compliance packaging or labeling does not conform to USP requirements	18VAC110-20-340	
25. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	
Repackaging, specialty dispensing, compounding:		
26. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	
27. Unit dose procedures or records not in compliance	18VAC110-20-420	
28. Robotic pharmacy systems not in compliance	18VAC110-20-425	

Minor Deficiency	Law/Regulation Cite	Conditions
29. Required compounding/dispensing/distribution records not complete and properly maintained; compounded products not properly labeled or assigned appropriate expiration date	54.1-3410.2	
Hospital specific or long-term care specific:		
30. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
31. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
After hours access or records not in compliance	18VAC110-20-450	
32. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	
33. ADD loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-550	
34. EMS procedures or records not in compliance	18VAC110-20-500	
35. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-560	
36. Maintaining floor stock in LTCF not authorized	18VAC110-20-520 and 18VAC110-20-560	

Project 2116 – Final exempt

BOARD OF PHARMACY

Correction of cite

18VAC110-20-106. Requirements for continued competency.

A. A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved continuing education for each annual renewal of registration. Hours in excess of the number required for renewal may not be transferred or credited to another year.

B. An approved continuing education program shall meet the requirements as set forth in subsection B of 18VAC110-20-90 or subsection B of 18VAC110-20-100.

C. Upon written request of a pharmacy technician, the board may grant an extension of up to one year in order for the pharmacy technician to fulfill the continuing education requirements for the period of time in question. The granting of an extension shall not relieve the pharmacy technician from complying with current year requirements. Any subsequent extension shall be granted for good cause shown.

D. Original certificates showing successful completion of continuing education programs shall be maintained by the pharmacy technician for a period of two years following the renewal of his registration. The pharmacy technician shall provide such original certificates to the board upon request in a manner to be determined by the board.

Part VII
Prescription Order and Dispensing Standards

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.

A. In addition to the acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time.

C. After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained on a pharmacy record for the required time period of two years, unless otherwise specified in regulation.

D. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

E. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist shall not return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.